## EXHIBIT C

## IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC.,

**MDL No. 2327** 

PELVIC REPAIR SYSTEM

PRODUCTS LIABILITY LITIGATION

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THIS DOCUMENT RELATES TO ALL WAVE ONE CASES INVOLVING THE PROLIFT LINE OF PRODUCTS

## RULE 26 EXPERT REPORT OF DR. ABBAS SHOBEIRI

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

## I. QUALIFICATIONS

Currently, I am a Professor of Obstetrics and Gynecology, Virginia

Commonwealth University School of Medicine & George Washington University,

Professor, Cell Biology & Anatomy, Graduate College, OUHSC, and Vice Chair,

Gynecologic Subspecialties, Inova Fairfax Hospital Women's Center. Previously, I was

Professor and Section Chief of Female Pelvic Medicine & Reconstructive Surgery at the

University of Oklahoma Health Sciences Center. I am also a Professor of Cell Biology

and Anatomy at the OUHSC.

I was recruited to the University of Oklahoma Health Sciences Center in 2002 as the first fellowship trained physician in Female Pelvic Medicine and Reconstructive Surgery in Oklahoma. Prior to settling in Oklahoma, I obtained my Bachelor degree from the University of Washington in Seattle, Medical Degree from Tufts University in Boston,

- 9. In a woman presenting with vaginal pain and sexual pain following a Prolift procedure, a mesh-related condition attributable to the mesh product is the most likely diagnosis on the list of differential diagnoses.
- 10. In a woman presenting with vaginal pain and sexual pain following a Prolift procedure, these symptoms are, more likely than not, associated with the properties of mesh described in this report.
- 11. The surgical management of mesh complications requires advanced training and specialized expertise.
- 12. Timely recognition and referral of mesh complications is of utmost importance to prevent prolonged suffering of patients.
- 13. Most patients with mesh complications are referred for treatment by someone other than the implanting doctor. This indicates that complications are underappreciated by community doctors and often results in a delay of appropriate treatment.
- 14. The Prolift devices are defectively designed as described in the body of this report.
- 15. Ethicon did not adequately warn physicians and patients about known complications and risks associated with its Prolift devices.
- 16. There are safer alternatives to the Prolift devics that have equivalent or superior efficacy.
- 17. Because of the rate and severity of complications and the lack of improved efficacy over other surgical procedures to treat pelvic organ prolapse, the risks of the Prolift devices outweigh their benefits and should not be used.

Ethicon's physician training program for the Prolift products was inadequate, and resulted in Ethicon's "certification" of numerous physicians who were undertrained and who lacked the experience, skills and expertise necessary to properly perform the implantation of these products.<sup>32</sup> Ethicon's documents reflect that Ethicon did not consider physician training to be a priority, or even a necessity.<sup>33</sup>

My personal experience with Ethicon was that I was approached as a "thought leader" to perform the Ethicon procedures. Identifying the "thought leaders" in the community was a popular industry strategy in convincing the community physicians to use their products which in part lacked credible efficacy and safety evidence. I did perform a few Prolifts all of which were associated with complications. I approached these complications quickly and resolved them by removing the mesh, but I have seen community physicians not properly informed of the complications, let the complications linger.

Particularly in light of Ethicon's knowledge about the risks inherent in the design of its products which Ethicon's internal documents specifically recognize, Ethicon's design of the Prolift products was unreasonably dangerous and defective. The Prolift devices failed to perform as safely as a patient or physician would expect when implanted in the intended manner, and the probability of a serious complication developing was so high that the risk of using the product outweighed any potential benefit.

Dated: January 29, 2016

S. Abbas Shobeiri, M.D.

Abbeit, MD

<sup>&</sup>lt;sup>32</sup> ETH.MESH.00005098; ETH.MESH.00847816; ETH.MESH.0409664; ETH.MESH.01184119.

<sup>&</sup>lt;sup>33</sup> ETH.MESH.00031538-00031560 ("Professional Education Events . . . Indicated by market analysis . . . Must have strong case for "Return on Investment"); ETH.MESH.00005098.